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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,330	08/22/2001	Carl Johan Friddle	LEX-0221-USA	9990

7590 03/04/2003

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EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/938,330	FRIDDLE ET AL.
Examiner	Art Unit	
	William W. Moore	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 December 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-11 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-5 and 7-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

- 4) Interview Summary (PTO-413) Paper No(s) _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

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DETAILED ACTION

Response to Amendment

Applicant's Amendments A and B, Papers Nos. 8 and 9 filed on December 10, 2002, have both been entered. The former canceled claim 1 and added the new claims 7-11 while the latter provided a revised copy of the Sequence Listing in both computer-readable and printed forms, bringing the application into compliance with the requirement stated at pages 2-3 of Paper No. 7 mailed September 6, 2002. The cancellation of claim 1 overcomes the rejection of record of that claim stated at pages 4 and 5 of Paper No. 7 under the second paragraph of 35 U.S.C. §112. The new claims 7-11 describe subject matter free of the prior art of record and claims 8-11 raise no new issues under the first or second paragraphs of 35 U.S.C. §112. Although Applicant's remarks accompanying the claim amendments of Paper No. 8 indicate, at page 2, Applicant's belief that claim 6 had been canceled, the non-elected claim 6 was not canceled in either Paper No. 8 or Paper No. 9, thus claims 2-11 remain pending herein. Because a new ground of rejection is stated herein, this communication is not made final.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-5 and 7-11 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility.

A claimed invention must possess a specific, substantial and credible *in vitro* or *in vivo* utility, but the instant application cannot identify any specific, substantial, utility for the invention described by the claims known to the inventors at the time the application was filed. It is agreed that polypeptides having the amino acid sequences of SEQ IDs NOs:20 and 22 share a significant degree of amino acid sequence homology with other, prior art, human metalloproteases. Claims 2-5 and 7 lack utility because there is no disclosure in

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the specification of any specific *in vitro* utility for an isolated nucleic acid sequence having the nucleotide sequence of either of SEQ IDs NOS:19 and 21, nor any disclosure of a specific *in vitro* utility for an isolated nucleic acid having a generic nucleotide sequence that encodes either of the amino acid sequences of SEQ IDs NOS:20 or 22. Neither does the specification indicate any specific *in vivo* utility for a nucleic acid encoding the amino acid sequences of either of SEQ IDs NOS:20 or 22. Claims 8-11 lack utility because the expression vectors and cells comprising the expression vectors can express no product having a specific utility where the specification discloses no specific utility for the encoded products, e.g., Applicant can identify no substrate recognized and cleaved by a protease *in vivo* or *in vitro* and can identify no specific cellular or extracellular function for either protease. While the specification proposes, at pages 7 and 8, potential diagnostic and prognostic uses for a claimed nucleic acid sequence these are not specific because there is no disclosure of what disease state or medical condition may or may not be diagnosed.

Although Applicant proposes, at pages 2 and 3, that the physiological function of the encoded products might be determined by constructing transgenic animals deficient in the expression of nucleic acid sequences encoding the amino acid sequences of either of SEQ IDs NOS:20 or 22, the specification discloses no specific physiological condition or state that implicates the lack of function or the aberrant function of either protease, and provides no suggestion of a physiological or cellular function for either native protease encoded by a claimed nucleic acid sequence. A method of use of a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Mere allegations of a prospective, potential, utility cannot rise to the level of a credible assertion of a specific *in vivo* utility that is substantial. Indeed, the specification's diffuse assertions indicate the contrary, that Applicant knew no specific utility for either native polypeptide encoded by

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claimed nucleic acid sequences at the time the application was filed that would permit an immediate use by the public of a disclosed nucleic acid sequence, or any use by the public of an expression vector or cell comprising a disclosed nucleic acid sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5 and 7-11 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite in its recitation of the phrase "drawn from the group" because the participle "drawn" does not indicate that a group embraced by the claim is the closed group intended by Applicant in the subsequent recitation "consisting of SEQ ID[s] NO[s]: 20 and 22". The intended group is not a group that may include non-selected, reserved, members that remain to be "drawn", rendering the scope of the intended subject matter ambiguous. An amendment that deletes the participle "drawn" and replaces it with the participle "selected" will overcome this rejection.

Allowable Subject Matter

Claims 2-5 and 7-11 are free of the prior art of record and are not affected by the effective priority date, December 12, 2000, of the published U.S. Patent Application 2002/0119555 of Bandaru et al. which date is subsequent to the September 19, 2000,

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filings date of Applicant's provisional application serial No. 60/233,796 wherein SEQ IDs NOS:20 and 22 were first disclosed as to which the instant application claims priority.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM-5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. The examiner's direct FAX telephone number is 703.746.3169. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.


William W. Moore
February 26, 2003